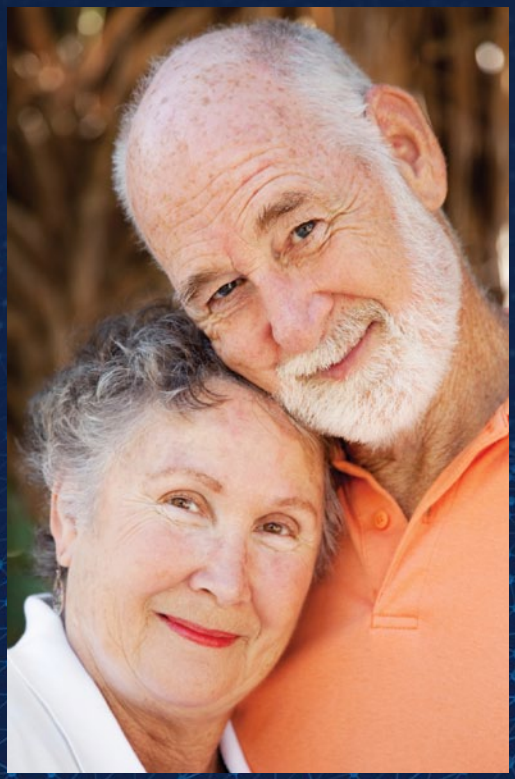
Nellix®

EndoVascular Aneurysm
Sealing System



A Patient's Guide to Abdominal Aortic Aneurysm Sealing and Repair

Endologix

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Introduction

This Patient's Guide has been provided to you on behalf of Endologix, Inc. The goal of this Guide is to help you learn more about your abdominal aortic aneurysm (AAA). You will learn about the symptoms of abdominal aortic aneurysms, how they are diagnosed, how they are treated, and what to expect after your surgery. As with any surgery, the best source of information and advice is your doctor. After reading this Guide, you may have questions to ask your doctor – page 13 provides space for you to write your questions. This Guide also provides definitions for medical terms indicated in **bold** throughout the Guide – refer to pages 10 and 11 for definitions of terms, as well as page 12 for additional information resources.

What is an Abdominal Aortic Aneurysm (AAA)?

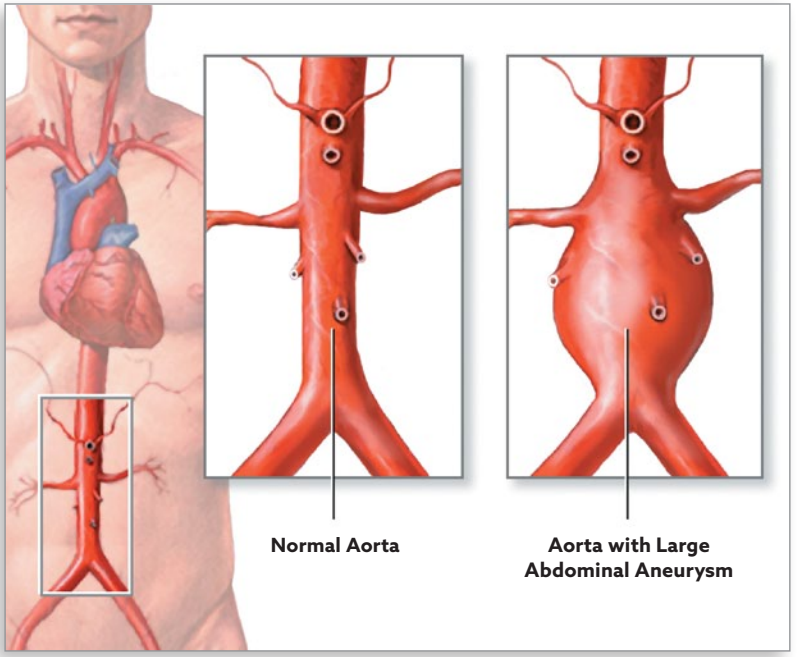
The **aorta** is the largest blood vessel in your body. It carries blood from your heart to the rest of your body. The aorta extends from the chest to the abdomen, where it branches into the **iliac arteries**. The iliac arteries carry blood to the lower parts of the body and to the legs. An **abdominal aortic aneurysm (AAA)** occurs when the portion of the **aorta** passing through the abdomen bulges because of a weakening of the vessel wall. The walls become thin and lose their ability to stretch. The weakened sections of the wall may become unable to support the flow of blood through it and can **burst**. When an **aneurysm** bursts, it causes serious internal bleeding.

What Causes an AAA?

The condition is fairly common in older adults and is more common in men than in women. Risk factors for developing it are age, smoking, family history of AAA, atherosclerotic disease, and high blood pressure.

What are the Symptoms of AAA?

Most patients diagnosed with AAA have no symptoms. However, for those patients that do have symptoms, the most common one is pain in the abdomen, back, or chest. The pain may range from mild to severe. In some patients, the pain in their abdomen spreads to their back. Others feel the **aneurysm** as a throbbing mass in their abdomen.



The AAA is often found during an examination for an unrelated health condition. During the examination, the patient may feel tenderness, back pain, abdomen pain, or pain in their legs. Your doctor may feel a bulge or throbbing in your abdomen. If you have been diagnosed with an AAA and you develop back pain, abdomen pain, muscle pain, weakness in the legs, or dizziness, call your doctor immediately, or go to the closest emergency room.

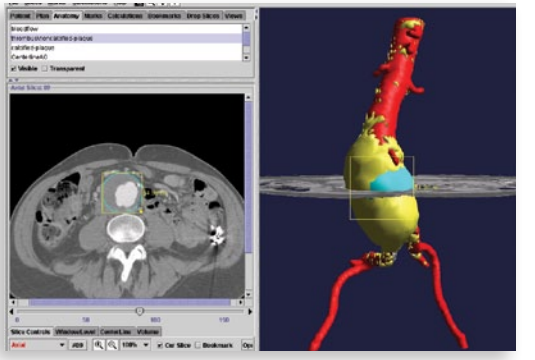
Is This a Serious Condition?
In the early stages, when the AAA is small in size, it may not be an immediate health risk to you. However, your doctor will want to check your condition on a regular basis to see if your AAA is growing. In later stages, if the AAA continues to grow, it needs to be treated in order to prevent it from bursting and causing serious internal bleeding. The risk of an **aneurysm** bursting increases as the aneurysm grows in size, and with high blood pressure. Aneurysms that **burst** are very serious and may be fatal.

AAA Diagnosis and Screening

If you have been diagnosed in the early stages with a small **aneurysm**, your doctor will recommend periodic examinations. Your doctor may also recommend regular screening if you have risk factors for developing an aneurysm (family history of AAA, high blood pressure, smoking and heart disease). This screening is commonly done with medical tests such as **CT scan**, **angiography**, and **ultrasound**. These tests can confirm the presence of the AAA and can determine its location, shape, size, and if it is in an early or late stage.

Treatment of Abdominal Aortic Aneurysm (AAA)

The goal of all AAA treatment is to prevent the **aneurysm** from bursting. The size and location of the aneurysm within your body, as well as your general health, will determine how your doctor treats it.



CT Scan **3D Reconstruction**

If your **aneurysm** is small, your doctor may only recommend regular examinations to monitor the size of the aneurysm. A large aneurysm, or one that is rapidly growing, poses a risk of bursting and requires treatment. There are now several options available for the treatment of **abdominal aortic aneurysms:**

Open Surgical Repair, Endovascular Aneurysm Repair (EVAR), and **Endovascular Aneurysm Sealing (EVAS)**

Open Surgical Repair

In **Open Surgical Repair**, the doctor makes a cut in the abdomen or side of the patient and repairs the section of the **aorta** that has an **aneurysm**. The repair is done by replacing the aneurysm section with a fabric tube called a graft. The graft is sewn into place with sutures and acts as a replacement blood vessel. This procedure requires stopping of the flow of blood through the aorta while the graft is being sewn in place. The surgery is performed under general anesthesia and takes about 2 to 4 hours to complete. Patients will usually stay overnight in the intensive care unit and another 5 to 7 days in the hospital. Depending on how your body heals, the overall recovery time may take up to 3 months or longer.

Open Surgical Repair is a well-known surgical procedure that works. However, it involves major surgery and is not well tolerated by all patients, depending on their overall health conditions. Additionally, Open Surgical Repair has a long recovery period, and with a risk that you may not return to full function after the recovery period. As with any medical procedure, Open Surgical Repair has a risk for complications. Ask your doctor about the risks of Open Surgical Repair as they relate to your own health conditions.

Endovascular Aneurysm Repair (EVAR)

Endovascular Aneurysm Repair, often called EVAR, is a minimally invasive alternative to Open Surgical Repair. With EVAR, instead of making a large cut in the abdomen, the doctor makes a small cut in each groin to gain access to the **femoral arteries** (blood vessels).

An **endovascular stent graft** is inserted through the small cut in the leg and placed inside the **aneurysm** in the **aorta**. Blood then flows through the endovascular stent graft rather than the weakened aneurysm part of the aorta. The endovascular stent graft remains inside the aorta permanently. The EVAR procedure may be done under local anesthesia and takes about 1 to 3 hours to complete. Patients will usually have a hospital stay of only a few days. Depending on how your body heals, the overall recovery time is usually 4 to 6 weeks.

Endovascular Aneurysm Sealing (EVAS)

Endovascular Aneurysm Sealing, or EVAS, is also a minimally invasive alternative to Open Surgical Repair. As in EVAR, instead of making a large cut in the abdomen, the doctor makes a small cut in each groin to gain access to the **femoral arteries** (blood vessels).

In EVAS, **endovascular stent grafts** each having an attached bag is inserted through both small cuts in the legs and placed

inside the **aneurysm** in the **aorta**. The doctor then injects a medical grade **polymer** material into the bags where it hardens to fill the entire aneurysm sac space. Blood then flows through the endovascular stent graft rather than the weakened aneurysm part of the aorta. The endovascular stent grafts with polymer-filled bags remain inside the aorta permanently. The EVAS procedure may be done under local anesthesia and takes about 1 to 3 hours to complete. Patients will usually have a hospital stay of only a few days. Depending on how your body heals, the overall recovery time is usually 4 to 6 weeks.

Not every patient is a candidate for EVAR or EVAS. As with any surgical procedure, EVAR and EVAS have risk of complications. Open Surgical Repair, EVAR, and EVAS all have advantages and disadvantages based upon each patient's health condition and needs. Ask your doctor about the possible risks of EVAS as they relate to your own health conditions.

What are the Advantages and Disadvantages of the Different Treatment Options?

Open Surgical Repair Advantages

- Standard method of treatment
- Well-proven surgical procedure
- Lasting results
- Long-term follow-up examinations of patient generally not required

Open Surgical Repair Disadvantages

- General anesthesia required
- Major abdominal surgery/long abdominal cut
- Surgical complication rate is higher than EVAR or EVAS
- Longer hospital stay and recovery time than EVAR or EVAS

EVAR and EVAS Advantages

- Minimally invasive procedures
- Local anesthesia may be used
- Lower surgical complication rate than **Open Surgical Repair**
- Shorter hospital stay and shorter recovery than Open Surgical Repair

EVAR and EVAS Disadvantages

- Higher potential for **endoleak** or **aneurysm** bursting than with **Open Surgical Repair**
- Long-term follow-up examinations are required
- Possibility of additional endovascular or surgical procedures.

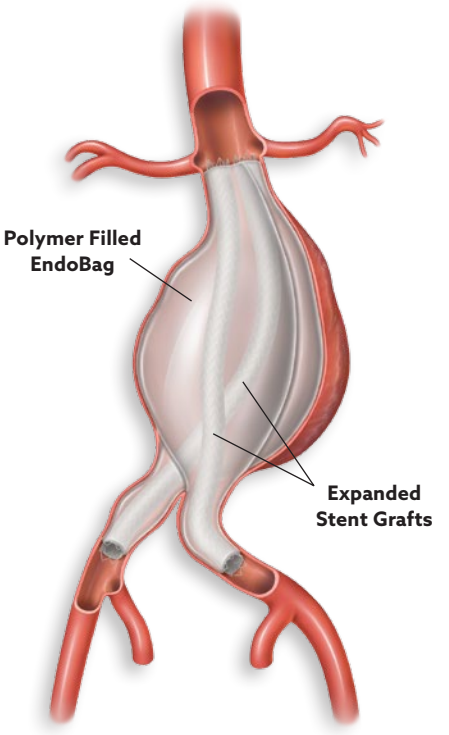
The Nellix® EndoVascular Aneurysm Sealing (EVAS) System

Your doctor has chosen the Endologix Nellix EVAS System to treat your **aneurysm**. Nellix is a **stent graft** with bags containing **polymer** material. It is called a stent graft because it has an internal metallic tube structure which is made of a cobalt chromium alloy and has a fabric covering

(called the graft) made of ePTFE, a Teflon® type of material. Two bags attached to the outside of each stent graft contain the polymer material.

How is Nellix Implanted?
The Nellix stent graft with attached bag is compressed into a long, thin plastic tube called a **delivery catheter**. Your doctor will insert thin wires into your **femoral arteries** through small cuts or punctures in each leg at the groin (see Figure A).

Two **delivery catheters** are inserted, one from each groin, and are advanced over the wire into position in your **aorta** (see Figure B). The **stent grafts** with attached bags are placed into position within your body so that they are positioned across the **aneurysm** of the aorta, with each extending from the aorta into the **iliac arteries**. When the stent grafts with attached bags are in proper position, the stent portion is expanded. The liquid **polymer** material is then injected by the doctor through the delivery catheter and into the bags surrounding the stent grafts (Figure C). As the bags fill with polymer, they expand to fill the aneurysm space. The polymer material then becomes solid within a few minutes. This expansion of the bags with the solid polymer is what holds the stent graft in place within your aorta. The wires and delivery catheters



are then withdrawn from the body. The stent grafts with polymer-filled bags reinforce the aorta that is weakened by the aneurysm and blood flows through the device to the arteries that go to the legs.

The doctor uses a visualization method during this process known as **fluoroscopy** (real time X-ray images) viewed on a monitor in order to place the polymer-filled **stent grafts** in the proper position within your body.

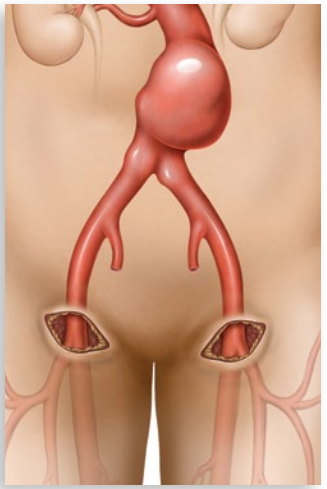


Figure A

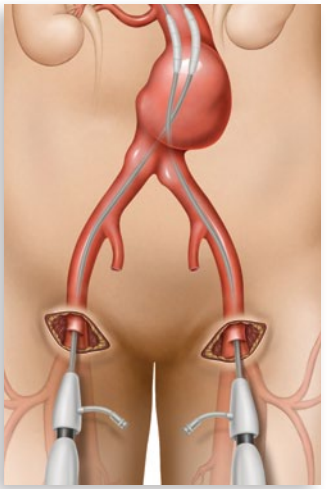


Figure B

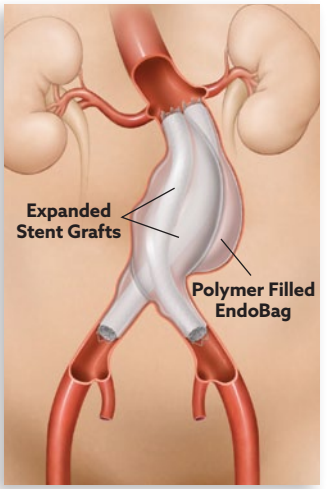


Figure C

Before the **Endovascular Aneurysm Sealing** procedure, your doctor will use diagnostic measurements (**CT scan**, **angiography**, and/or **ultrasound**) of your **aorta** to visualize the **aneurysm** and to select the proper lengths of the **stent grafts** to fit your body. During the procedure, your doctor will confirm the correct position of the implants and the complete sealing of blood flow from the aneurysm using X-ray angiography before closing the cuts or punctures in your legs with a few sutures.

As always, X-ray types of imaging, **CT scans**, and **angiograms** carry potential risks of either radiation exposure, or allergic reactions related to the **contrast dye** used during the tests. The occurrence of an allergic reaction to the contrast dye is a rare condition. The benefits of these tests in viewing your **abdominal aortic aneurysm** far outweigh the risk posed by the test. Speak with your doctor about any concerns you may have about the follow-up tests.

What Should I Expect After the Endovascular Procedure?

Endovascular Aneurysm Sealing may result in less discomfort, shorter procedure times and hospital stays and faster recovery in comparison to **Open Surgical Repair.** Your hospital stay may be only a few days. You may be able to return to your normal activities

within 4 to 6 weeks after the procedure. Endovascular Aneurysm Sealing requires regular follow-up examinations by your doctor.

Why is Follow-up Important?

There are some problems associated with EVAR or EVAS which cannot be felt. The most serious of these would be continued **aneurysm** growth. This is why your regular follow-up examinations are so important.

Below is a list of problems that could lead to continued **aneurysm** growth:

Endoleak - occurs when blood from the **aorta** continues to leak into the **abdominal aneurysm**. Most endoleaks cannot be felt and do not require treatment. However, an endoleak may lead to aneurysm growth and should be carefully followed over time. A small number of endoleaks require further treatment.

Graft movement - this is when the position of the **stent graft** after placement in your body shifts over time. You cannot feel when the graft moves, however it can be seen with a **CT scan**.

Your doctor will order regular follow-up examinations with medical tests such as a physical exam, **CT scan**, **angiography**, and/or **ultrasound** to view the results of your treatment and any changes that may occur over time. It is important that you go to all of the follow-up examinations recommended by your doctor. These examinations are generally required at one month, six months, one year, and yearly thereafter following your AAA procedure. Your doctor may require additional follow-up tests based on the findings at the regular follow-up visits.

When Should I Call My Doctor?

Although most of the problems associated with **Endovascular Aneurysm Sealing** cannot be felt, call your doctor immediately if you experience any of the following symptoms, or go to the closest emergency room. The following symptoms are the most common potential problems as a result of your **EVAR** or **EVAS** procedure:

Aneurysm growth - symptoms are:

- Pain in the legs, back, chest or abdomen
- Numbness in the legs, back, chest, or abdomen
- Weakness in the legs, back, chest, or abdomen

Aneurysm bursting (rupture) - a very serious condition that results in internal bleeding. Symptoms are:

- Dizziness
- Fainting
- Rapid heartbeat
- Sudden weakness

Stent Graft Blockage - symptoms are:

- Pain in the legs or hip during walking
- Discoloration or coolness in the leg

What if I Need Magnetic Resonance Imaging (MRI)?

Following implantation with the stent graft, it is still safe for you to have most **MRI** procedures. MRI safety information is provided on your Nellix Card. Be sure to tell all of your healthcare providers that you have a **stent graft** and show them your Nellix Card.

Definition of Medical Terms

Abdominal Aortic Aneurysm (AAA) - a ballooning (enlarging or thinning) that occurs in the part of the aorta that passes through the abdomen (stomach area). The ballooning is due to a weakening in the arterial wall.

Aneurysm - a ballooning (enlargement of the vessel diameter and/or thinning of the vessel wall) of a weakened area of a blood vessel.

Angiography/Angiogram - angiography is an X-ray method that uses contrast (dye) injected into the bloodstream to see blood flow through blood vessels. The resulting image is an angiogram.

Aorta - the main artery that carries blood from the heart to the rest of the body.

Biocompatible - not harmful to living tissue.

Burst - a tear in the vessel wall that allows blood to spill into the abdominal cavity resulting in serious internal bleeding. This type of tear may occur in the location of the ballooning of an aneurysm.

Contrast Dye - a drug that is injected into the blood system to show blood flow through the blood vessels under X-ray types of imaging or CT scan.

CT Scan (Computed Tomography Scan) - an imaging technique that creates a series of computerized x-rays that form a picture of your aneurysm. Also known as a "CAT scan."

Delivery Catheter - a long, thin tube-like device that the doctor uses in delivering and positioning the stent graft during an endovascular procedure.

Endoleak - blood flow into the abdominal aortic aneurysm after placement of a stent graft.

Endovascular Stent Graft - a stent graft placed within a diseased vessel to repair an aneurysm without the use of Open Surgical Repair.

Endovascular Aneurysm Repair (EVAR) - involves the placement of an endovascular stent graft to seal off an aneurysm and create a new blood flow path. It is considered to be a less invasive approach than Open Surgical Repair.

Endovascular Aneurysm Sealing (EVAS) - involves the placement of an endovascular stent graft with attached bags that are filled with a polymer material to seal off the entire aneurysm sac and create a new blood flow path. It is considered to be a less invasive approach than Open Surgical Repair.

ePTFE - A synthetic Teflon® type of material commonly used in medical devices; an acronym for expanded polytetrafluoroethylene.

Femoral Arteries - two blood vessels (one in each leg) that carry blood to the thigh region. Doctors can use the femoral arteries as a path to reach the iliac arteries and the aorta during EVAR or EVAS.

Fluoroscopy - a real time X-ray image that is viewed on a monitor. The doctor generally uses fluoroscopy to visualize the placement of the endovascular stent graft during an EVAR or EVAS procedure.

Iliac Arteries - two large blood vessels (called femoral arteries), in each leg which connect to the lower end of the aorta.

MRI (Magnetic Resonance Imaging) - an imaging technique that uses magnetic fields and radio waves to form detailed images of structures within the body.

Open Surgical Repair - A type of surgery performed to repair an aneurysm. To reach the aneurysm, a doctor makes a large cut through the abdomen of the patient. The doctor repairs the aorta by replacing the aneurysm section with a fabric tube called a "graft." The "graft" is sewn into place and acts as a replacement blood vessel.

Polymer - a chemical compound or mixture of compounds consisting essentially of repeating structural units.

Renal Arteries - arteries that supply blood flow to the kidneys.

Stent - metal part of the stent graft that provides internal support and holds the stent graft in place.

Stent Graft - a type of endovascular graft with a metallic stent inside the internal structure of the graft fabric cover.

Stent Graft Blockage - when the limbs of the stent graft become blocked and limit the amount of blood that can flow through the stent graft. This is an undesirable condition that may be felt as pain, weakness, or numbness in the legs.

Ultrasound - an imaging technique used in follow-up of EVAR or EVAS that creates an image through the use of high-frequency sound waves.

Where Can I Get More Information?

VascularWeb Patient Information
Website: www.vascularweb.org
VascularWeb is an internet-based global resource of information and service for individuals interested in improving vascular health worldwide. VascularWeb is sponsored and owned by the American Association for Vascular Surgery (AAVS) and the Society for Vascular Surgery (SVS), both non-profit organizations.

Interventional Therapy

Society of Interventional Radiology
Website: www.sirweb.org
The Society of Interventional Radiology (SIR) is a professional society for doctors who specialize in interventional or minimally invasive procedures. SIR is a non-profit, national organization deeply committed to its mission to improve health and the quality of life through the practice of cardiovascular and interventional radiology.

U.S. National Library of Medicine
Website: www.medlineplus.gov
The National Library of Medicine (NLM), on the campus of the National Institutes of Health in Bethesda, Maryland is the world's largest medical library. The library collects materials in all areas of biomedicine and health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life and social sciences.

Contact Information

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Endologix Inc., located in Irvine, California, is engaged in the development of minimally invasive therapies for the treatment of aortic aneurysms.

Questions for My Doctor

This part of the Guide is provided for you to list any questions that you may have for your doctor. Your doctor is your best source of information and can help you evaluate your treatment options based on your own physical health conditions and needs. You may also want to use this space to keep a record of your discussions with your doctor.

www.endologix.com/ContactUs

INDICATIONS FOR USE: The Nellix® EndoVascular Aneurysm Sealing System can be used in patients who have an infrarenal abdominal aortic or aortoiliac aneurysm (AAA) with suitable anatomy as indicated below:

- Iliac and femoral artery access that allows for atraumatic device introduction
- Aortic proximal neck diameter range of 18 mm to 32 mm
- Minimum aortic proximal neck length ≥ 10 mm
- Proximal aortic neck angulation of ≤ 60°
- Aortic aneurysm with a blood lumen diameter ≤ 70 mm
- Iliac arteries luminal diameter range of 9 mm to 35 mm

CONTRAINDICATIONS: The Nellix® EndoVascular Aneurysm Sealing System is contraindicated for patients who have a condition that threatens to infect the implant and patients with sensitivities or allergies to the implant materials. Note: Nellix System (Catheter delivery and Implant) are not made with natural rubber latex.

Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings, and precautions. Rx only.

NOTE: Endologix products and associated components are not available in all countries or regions. Please contact your Endologix representative for details regrading product availability.

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